UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,624	01/26/2000	Carlos Picornell Darder	4948-2PCIP	8816

7590 09/12/2003

THOMAS C. PONTANI, ESQ.
COHEN PONTANI LIEBERMAN & PAVANE
551 FIFTH AVENUE
SUITE 1210
NEW YORK, NY 10176

EXAMINER	
PULLIAM, AMY E	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/491,624	Applicant(s) DARDER, CARLOS PICORNELL	
	Examin r Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears n the cover sheet with the correspond nc address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment E and the Extension of Time, both received by the Office June 30, 2003.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-13, and 15-34 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,132,771 to Depui *et al.*.

Depui *et al.* disclose an oral pharmaceutical dosage form comprising a proton pump inhibitor (abstract). More specifically, Depui *et al.* teach that the proton pump inhibitor can be selected from omeprazole, lansoprazole, pantoprazole, pariprazole, and leminoprazole (c 5-6). Additionally, Depui *et al.* teach that the core material for their composition is a seed layered with

the proton pump inhibitor (c 8, l 48-50). Depui *et al.* also teach that the seeds can be made of different materials, including sugars (c 8, l 57). Depui *et al.* also teach that the proton pump inhibitor can be mixed with other components prior to layering on the seeds, wherein the components can include binders, surfactants, disintegrating agents, and fillers (c 9, l 1-5). The binder can be selected from HPM, HPMC, CMC, PVP, sugars and starches (c 9, l 3-6). The alkaline substance can be selected from sodium potassium, calcium, magnesium, and aluminum salts of phosphoric acid, carbonic acid, citric acid, and other weak acids, as well as magnesium oxide substances, and other substances normally used in antacid compositions (c 9, l 27-42). The surfactant can be sodium lauryl sulfate (c 9, l 10). Depui *et al.* also teach that the seeds have a size between 0.1 and 2 mm, which equals 100 to 2000 micrometers (c 8, l 62). Most importantly, Depui *et al.* teach that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Depui *et al.* teach that a middle, separating layer is optional, as the enteric coating can be applied directly to the coated core (c 9, l 46-50 and c 10, l 41-43). The enteric coating layer can be selected from HPMCP, methacrylic acid polymers, HPMC acetate succinate, shellac, and others (c 1,l 46-53). The enteric coating layer can also comprise a plasticizer such as PEG or cetyl alcohol (c 10, l 58-60). Therefore, the teachings of Depui *et al.* anticipate the limitations of applicant's instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13, and 15-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui *et al.*, as discussed above, and in view of the following comments. Depui *et al.* is discussed above as teachings an oral pharmaceutical composition comprising a proton pump inhibitor and an enteric coating. Depui *et al.* does not necessarily state that there can be no separating layer between the enteric coating layer and the coated seed. However, Depui *et al.* do teach that one of their embodiments is to coat the seed with the active layer, and then directly coat that with an enteric layer. One of ordinary skill in the art would have been motivated to make an oral composition comprising an inert core, an active coating, and an enteric coating, without the presence of a separating layer, based on the teachings of Depui *et al.*. The expected result would be a successful composition for the treatment of gastrointestinal disorders. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui *et al.*, as applied to claims 1-13, and 15-34 above, and further in view of Lovgren *et al.*.

Applicant has added new claim 35, requiring the formulation to contain only one active ingredient. Lovgren *et al.* is relied upon for the teaching that it is known in the art to create formulations comprising a core of a proton pump inhibitor as the single active, wherein the core is coated with the necessary coatings. It is the position of the examiner that one of ordinary skill in this type of pharmaceutical art would be motivated to use a proton pump inhibitor by itself, if that would achieve the desired effect. It is further the position of the examiner that this does not

render patentability to the instant claims. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that Depui does not anticipate, identify, or enable one of ordinary skill in the art to make the invention without undue experimentation. Applicant argues that the main objective of Depui is to provide an oral dosage form simultaneously containing both an acid suppressive agent and a prokinetic agent, but not enteric coating layered preparations of proton pump inhibitors. The examiner does not find this argument persuasive. As previously discussed, Depui clearly teach (as stated in the abstract of the patent), "[a]n oral pharmaceutical dosage form comprising a proton pump inhibitor and one or more prokinetic agents in a fixed formulation, wherein the proton pump inhibitor is protected by an enteric coating layer." [Emphasis added]. It is the position of the examiner that this passage clearly demonstrates that Depui is teaching enterically coated proton pump inhibitors, regardless of whether of not that is the main objective of their patent.

Additionally, as stated previously, applicant argues that Depuit has 14 examples, and each of them teaches a separating layer between the core and the enteric coating. However, applicant's and patentees are never held to simply what is covered in their examples. This would defeat the purpose of the specification. Additionally, the examiner points to several passages within the DePui reference First, DePui teaches that "before applying the enteric coating layer onto the core material... the pellets or tablets may optionally be covered with one or more

separating layers" Emphasis added, column 9, lines 47-50. Additionally, at column 10, lines 42-43, Depui teaches that the enteric coating materials can be applied onto the core material OR onto the core material covered with separating layers. Lastly, claim 1 of the Depui patent teaches a formulation comprising pellets covered with an enteric coating layer. There is no requirement for a separating layer in claim 1 of the Depui reference. Applicant's next line of arguments discuss the "505 patent" in detail. This "505 patent" is briefly mentioned in the Depui reference as an example of a reference teaching the importance of protecting proton pump inhibitors with enteric coatings. Applicant has taken this small reference to the "505 patent" and relied upon it to attempt and overcome the instant rejection. However, the examiner points out that this reference to the "505 patent" is a very small reference, and is mentioned only to show related formulations in the art. The passage is not used to show Depui's preferred embodiment.

Applicant argues that the "505 patent" discloses compositions having a core containing the PPI and an alkaline substance, one or more separating layers, and an outer enteric coating. This argument is not found to be persuasive, because the examiner did not rely upon the "505 patent" as prior art, instead, the examiner relied upon the Depui reference.

Applicant states that Depui fails to describe how a stable and useful oral form of a PPI can be made without having an alkaline reacting substance and at least one separating layer. Applicant further argues that Depui is not enabled for this type of composition. Applicant further states that the word "optional" does not make the Depui disclosure enabling for a composition without a separating layer. The examiner respectfully disagrees with the above assertions. First, the Depui reference clearly teaches that the separating layer is optional (see c 9, l 47-50). Furthermore, it is the position of the examiner that one skilled in the art would not use

a separating layer, if a separating layer was not necessary. Applicant has provided no evidence that a separating layer is necessary for the Depui formulation, particularly because Depui himself states that said layer is optional. Applicants have provided no unexpected results found by omitting a layer which the reference clearly states is optional. In order to show any unexpected results over the Depui reference, Applicant should have compared the Depui formulation with a separating layer with the Depui formulation without a separating layer. This would allow the Office to determine whether Depui's formulation would be successful both with and without the separating layer. If, in order to make a stable formulation without a separating layer, according to the methods and components taught by Depui, other changes must be made to the composition and its method of preparation, this type of evidence might be a way to show unexpected results. However, the Office's point of view is as follows. The Depui reference clearly teaches coating a PPI with an enteric coating, and optionally placing a separating layer in between. This clearly teaches two formulations; one with a separating layer, and one without the separating layer. One of ordinary skill in the art would make the composition of Depui without the separating layer, because the reference itself teaches this is acceptable. If Applicant can show that the formulation of Depui is not stable without the presence a separating layer, then this might constitute a showing of unexpected results.

The test is not whether or not the prior art is able to produce a working model. Instead, the test is what information has been placed into the public domain, and would one of ordinary skill in the art would gain from the reference. It is the position of the examiner that a formulation chemist would be able to, through routine and conventional experimentation,

determine the method necessary to provide an enteric layer of a drug. This is particularly true based on the reference's teaching that the drug can be coating with an enteric coating.

Applicant's argument that the prior art would not enable one skilled in the art to create the claimed invention is not found persuasive, especially given the broad scope of Applicant's claims, which permit the presence of any plasticizer, any surfactant, any pigment, and any lubricant.

Furthermore, the examiner points out that Applicant's claim 1 is drawn to several different classes of compounds. Applicant places a great deal of emphasis on the stability of the compounds. It is recommended that Applicant provide data relating to each of the classes of compounds found in claim 1, in order to provide arguments which are commensurate in scope with the independent claim. Currently, Applicant has not shown that one can formulate a stable composition with each of the claimed classes of active compounds.

Additionally, Applicant spends a great deal of time discussing a reference (EP 642797) which was also not relied upon by the examiner. Therefore, the assertions made relating to this reference are not considered to be relevant. Furthermore, the Declaration is comparing a related foreign application with this EP reference, which again, was not relied upon by the examiner. In order to be persuasive, Applicant should submit a declaration comprising comparative data which pertains to the rejections set forth by the Office.

Furthermore, Applicant has submitted tables showing comparisons between the '771 patent and the '505 patent. The examiner, however, does not find such showings to be persuasive. The examiner still relies upon the above assertions, that the '771 clearly teaches that the presence of a separating layer is optional. As this is the only differentiating limitation

between the composition of the claimed invention, and that of the prior art, the examiner sees no patentable distinction.

Applicant asserts that table 5 shows that formulations comprising a stabilizing layer were stable, while formulations without a stabilizing layer had stability problems. This argument is not found to be persuasive, because there are no limitations drawn to stability requirements in most of claims. The claims that do discuss stability, specifically, claims 39 and 40, do not overcome this argument, because stability is a term of relativity. Without a more specific limitation discussing what exactly is meant by "stable," this limitation does not render patentability. The above discussed table just proves that formulations without stabilizing layers were discussed in the art. The examiner again suggests that Applicant amend the claims to more specifically state the invention, because as claimed, the broad claims are still rendered unpatentable by the cited art.

Lastly, the examiner does not find the process claims patentable over the prior art because they contain comprising language, will allows for the inclusion of additional steps.

For the above reasons, this rejection is maintained.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 5,364,636 and US Patent 5,176,909. Both references are cited to show that prior to 1996, formulations and methods using enteric coatings directly applied to the active layer, were known in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
AU 1615
September 11, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600